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10/517,039	12/07/2004	Rafiqul Khan	70094USPCT	7399

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

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08/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,039	KHAN, RAFIQUL	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *19-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/15/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-22 are pending.

2. Applicant's election without traverse of Group I, claims 1-18 in the reply filed on 5/29/2007 is acknowledged.

Claims 19-22 are withdrawn from consideration for being drawn to a non-elected invention.

3. Claims 1-18 are examined in the present office action.

Oath/Declaration

4. The Oath and Declaration is objected to because provisional application 60/390,562 is listed incorrectly as a 'Prior Foreign Application Number(s)'.

Application Data Sheet

5. The Application Data Sheet is objected to because Applicant lists the present application as a 'Non-Provisional of' 60/390,562 filed 6/22/2002. The Office contends that to claim benefit to a provisional application, a non-provisional application has to be filed within one year of filing the provisional application. Applicants also list the present application as 'PCT of' PCT/US03/19212. The present application is a --371 of-- PCT/US03/19212, which --claims benefit to-- 60/390,562.

Specification /Priority

6. Objection is made to the specification for improperly claiming the benefit of a provisional application. 37 CFR 1.78(a)(5)(i) requires that any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed provisional applications must contain or be amended to contain a reference to each such prior-filed provisional application, identifying it by the provisional application number (consisting of series code and serial number). Amending the first paragraph of the specification to recite "This application is the National Stage of International Application No. PCT/US03/19212, filed 6/17/2003, which claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application 60/390,562, filed 06/22/2002" will obviate the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

Claims 1 and 18 are indefinite for reciting "leaving primary leaves attached to a remaining cotyledon". Primary leaves arise from a stem or epicotyl and do not arise from cotyledons. See for example Figure 4.

Claims 1 and 18 are indefinite for reciting "a portion". Applicants have not set forth the metes and bounds of this term.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for transforming soybean cells or tissue or a method for producing a stably transformed soybean plant comprising imbibing soybean seeds overnight, followed by removing the seed coat, followed by removing part of the hypocotyl, keeping about 0.5 cm of the hypocotyl and removing one cotyledon along with it adjacent axillary shoot bud, this is followed by removing the primary leaves so that the leaf bases are still present on the epicotyl. The prepared explants are co-cultivated with Agrobacterium carrying the desired genes of interest, for 2-5 days on medium comprising B5 salts and vitamins, sucrose, BAP, GA3 and MES followed by washing the explants and selecting transformed plants by culturing the co-cultivated explants on medium comprising MS salts and B5 vitamins, BAP, ticarcillim, cefotaxime, sucrose, followed by cultivation on medium comprising the previously mentioned constituents and including GA3, and IBA and selecting shoots growing from the primary leaf base which were rooted on medium containing salts, vitamins, a selection agent, sucrose and IBA, does not reasonably provide enablement for a method for transforming soybean cells or tissue or a method for producing a stably transformed soybean plant comprising method steps that only recite explant preparation without including the specifics of the media that is used during the cultivating and regeneration steps. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method for transforming soybean cells or tissue or a method for producing a stably transformed soybean plant comprising preparing an explant from a soybean seed by removing one cotyledon along with its adjacent axillary bud, removing a portion of a primary leaf, thereby generating a primary leaf base, and co-cultivating said explant with Agrobacterium comprising at least one nucleic acid of interest, or wherein at least one formed shoot is cultivated in a medium comprising a selection agent, or wherein the nucleic acid comprises a selectable marker gene, or wherein shoot formation is induced from said primary leaf base, or wherein shoot formation is induced by culturing said primary leaf base in a medium comprising a shoot-inducing hormone, or wherein said hormone is at least one of an auxin, cytokinin and a gibberellic acid, or wherein the auxin is IAA or wherein the cytokinin is benzylaminopurine (BAP), or wherein shoot formation comprises removing a primary meristem,

or wherein a shoot is selected, or wherein a selected shoot is grown into a soybean plant, or wherein the seed is a mature seed, an immature seed or a germinated seed.

The state-of-the-art teaches that specific conditions and chemical components are required to achieve a successful transformation of a plant. Hansen et al (1999, Trends in Plant Science 4(6):226-231) teach that successful transformation of plants demands that certain criteria be met (page 227, under "Transformation systems"). Some of the requirements are that target tissues are competent for propagation or regeneration, an efficient DNA delivery method, and the ability to recover fertile transgenic plants at a reasonable frequency. Hansen et al also teach that there are variables that need to be tested to ensure success. These variables include the use of feeder cells, alternative *Agrobacterium* strains, infiltration of the bacteria, and the duration and temperature of co-cultivation (page 228, right column, 3rd paragraph). Hansen also teaches that some crops appear to react or be hypersensitive to *Agrobacerium* and form necrotic barriers. To overcome this reaction, the addition of antioxidants is required (page 228, right column, last paragraph).

The Office contends that Applicants' independent claims do not contain all the necessary steps and media that are required to transform and regenerate transgenic soybean plants. It is known in the art that each species of plant has a unique requirement of salts and hormones that are required for regeneration, including a carbon source. Therefore, independent claims that do not recite the full assortment of growth promoting compounds, i.e., salts, vitamins, hormones and a carbon source, are not enabled.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to use the method recited in Applicants' independent claims and

then make all the different possible combinations of media comprising all the different kinds of salts, vitamins, hormones, carbon sources and additional additives, e.g., different amino acids, and cultivating explants that have been in contact with Agrobacterium, to identify those, if any, that form a transgenic regenerated shoot that can be further rooted and that produce seed that are transformed.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 7-15 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hinchee et al (1999, U.S. Patent Number 5,959,179).

The claims are drawn to a method for transforming soybean cells or tissue or a method for producing a stably transformed soybean plant comprising preparing an explant from a soybean seed by removing one cotyledon along with its adjacent axillary bud, removing a portion of a primary leaf, thereby generating a primary leaf base, and co-cultivating said explant with Agrobacterium comprising at least one nucleic acid of interest, or wherein at least one formed shoot is cultivated in a medium comprising a selection agent, or wherein the nucleic acid comprises a selectable marker gene, or wherein shoot formation is induced from said primary leaf base, or wherein shoot formation is induced by culturing said primary leaf base in a medium comprising a shoot-inducing hormone, or wherein said hormone is at least one of an auxin,

cytokinin and a gibberellic acid, or wherein the auxin is IAA or wherein the cytokinin is benzylaminopurine (BAP), or wherein shoot formation comprises removing a primary meristem, or wherein a shoot is selected, or wherein a selected shoot is grown into a soybean plant, or wherein the seed is a mature seed, or a germinated seed.

Because of the 112 2nd paragraph indefiniteness for "a portion" as discussed above, the Office interprets "a portion" of a primary leaf to include any part of the primary leaf including all of it.

Hinchee et al teach a method for producing a transformed soybean plant comprising preparing explants by removing the seed coat from the germinated seedlings and cutting the hypocotyl so as to remove the lower end and root axis. Hinchee et al disclose the remaining hypocotyl was split down the axis and then the primary leaves and primary shoot meristem were removed. Hinchee discloses the prepared explant was added to a single Petri dish and Agrobacterium was added to cover the explant (column 91, lines 1-20). Hinchee et al disclose the Agrobacterium strain used to transform soybean comprised a transformation vector comprising the EPSPS gene which confers glyphosate resistance (column 87, line 45 to column 88, line 9). Hinchee et al disclose the explants that were co-cultivated with Agrobacterium were cultured on culture medium comprising 6-benzylaminopurine (BAP), glyphosate, a selection agent, gibberillic acid, IAA (column 91, lines 58-67). Hinchee et al disclose that "Identification of putative A3237 transgenics (elongating, normal appearing shoots) required approximately 8-20 weeks (column 92, lines 25-27). Hinchee et al disclose shoots were rooted on media and then transferred to 2 inch pots (column 92, line 36). The Office interprets the removal of primary

leaves to mean that the primary leaf base is exposed and the seeds of Hinchee et al are mature and germinated and as such, Hinchee et al anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hinchee et al (1999, U.S. Patent Number 5,959,179) for claims 1-3, 7-15 and 16-18 taken with Villand et al (1999, U.S. Patent Number 5,977,437).

The claims are drawn to a method for transforming soybean cells or tissue or a method for producing a stably transformed soybean plant comprising preparing an explant from a soybean seed by removing one cotyledon along with its adjacent axillary bud, removing a portion of a primary leaf, thereby generating a primary leaf base, and co-cultivating said explant with Agrobacterium comprising at least one nucleic acid of interest, or wherein at least one formed shoot is cultivated in a medium comprising a selection agent, or wherein the nucleic acid comprises a selectable marker gene, or wherein shoot formation is induced from said primary leaf base, or wherein shoot formation is induced by culturing said primary leaf base in a medium comprising a shoot-inducing hormone, or wherein said hormone is at least one of an auxin, cytokinin and a gibberellic acid, or wherein the auxin is IAA or wherein the cytokinin is

benzylaminopurine (BAP), or wherein shoot formation comprises removing a primary meristem, or wherein a shoot is selected, or wherein a selected shoot is grown into a soybean plant, or wherein the seed is a mature seed, or a germinated seed.

Claims 4-6 and 16 are drawn to the above method wherein the selectable marker gene is a phosphomannose isomerase gene, or wherein the selection agent is mannose or wherein co-cultivation with Agrobacterium is carried out in the presence of mannose, or wherein said soybean seed is an immature seed.

The teachings of Hinchee et al have been discussed above.

Hinchee et al do not teach the selectable marker gene is a phosphomannose isomerase gene, or wherein the selection agent is mannose or wherein co-cultivation with Agrobacterium is carried out in the presence of mannose, or wherein said soybean seed is an immature seed.

Villand et al disclose the use of phosphomannose isomerase gene is used as a selection marker to select transgenic shoots on a media containing D-mannose as the carbon source (column 14, lines 45-53).

Given the recognition of those of ordinary skill in the art of the value of transforming soybean, e.g., for crop improvement, one of ordinary skill in the art would use the method of Hinchee et al of soybean transformation and one of ordinary skill in the art would be motivated to modify the method of Hinchee et al by using a different selectable marker of phosphomannose isomerase as disclosed by Villand et al. The motivation for using the marker of Villand et al comes from the general knowledge of one of ordinary skill in the art of trying new selection markers to optimize or improve a particular method. One of ordinary skill in the art would also optimize process parameters by using immature soybean seeds in the transformation process.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
August 16, 2007

STUART F BAUM, PH.D
PRIMARY EXAMINER